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LEXICON PHARMACEUTICALS, INC.
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BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES

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*Ex parte* D. WADE WALKE, JOHN SCOVILLE,
GREGORY DONOHO, and C. ALEXANDER TURNER, JR.

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Appeal 2009-010123
Application 09/863,823
Technology Center 1600

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Decided: November 16, 2009

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Before DEMETRA J. MILLS, ERIC GRIMES, and FRANCISCO C. PRATS, *Administrative Patent Judges*.

GRIMES, *Administrative Patent Judge*.

DECISION ON APPEAL

This is an appeal under 35 U.S.C. § 134 involving claims to nucleic acids, which the Examiner has rejected for lack of patentable utility. We have jurisdiction under 35 U.S.C. § 6(b). We affirm.

## STATEMENT OF THE CASE

The Specification discloses "human polynucleotides encoding proteins that share sequence similarity with animal membrane proteins" (Spec. 1: 8-10).

Claims 1-4 and 6-13 are pending and on appeal. The claims have not been argued separately and therefore stand or fall together. 37 C.F.R. § 41.37(c)(1)(vii). Claim 1 is representative and reads as follows:

1. An isolated nucleic acid molecule comprising a nucleotide sequence encoding the amino acid sequence of SEQ ID NOS: 2 or 6.

## UTILITY

*Issue*

The Examiner has rejected claims 1-4 and 6-13 under 35 U.S.C. §§ 101 and 112, first paragraph, for lack of patentable utility (Ans. 3, 7-8). The Examiner finds that the Specification does not disclose how much similarity there is between the proteins encoded by the claimed nucleic acids and known proteins (*id.* at 4), nor does it disclose any biological activity for the encoded proteins or any connection with any physiological condition or disorder (*id.* at 5); therefore, "using it as a research tool to develop therapeutics does not provide it with a substantial or specific utility" (*id.* at 6-7). The Examiner finds that "the claimed nucleic acid and the encoded polypeptide do not have a substantial utility because basic research is required to study the properties and activity of the claimed polynucleotide and encoded protein" (*id.* at 7).

Appellants contend that the claimed nucleic acids have utility in "diagnostic assays, such as forensic analysis" (Appeal Br. 4), in "assessing

gene expression patterns using high-throughput DNA chips" (*id.* at 9) and in mapping the human genome (*id.* at 11-12).

The issue presented is: Did the Examiner err in concluding that none of the uses asserted for the claimed nucleic acids satisfy the requirements of 35 U.S.C. § 101?

*Findings of Fact*

1. The Specification discloses that "[m]embrane proteins and secreted proteins can act in concert to regulate a variety of physiological and biochemical functions in the body" (Spec. 1: 22-24).

2. The Specification discloses that SEQ ID NO: 2 has 254 amino acids (*id.* at 2: 7-9).

3. The Specification discloses that SEQ ID NO: 6 has 262 amino acids (*id.*).

4. The Specification discloses that the proteins encoded by SEQ ID NOs 2 and 6 "share structural similarity with eukaryotic membrane and secreted protein[s], including, but not limited to neural cell adhesion molecules (NCAMs), tyrosine kinase receptors, and vascular endothelial growth factor (VEGF) receptors as well as a variety of homologues and orthologs across a range of phyla and species" (*id.* at 2: 1-6).

5. The Specification discloses that "[i]n addition to human NCAMs, the described [proteins] also share significant similarity with NCAMs (via the Ig-like domain) from a range of phyla and species" (*id.* at 16: 22-24).

6. The Specification discloses that SEQ ID NOs 2 and 6 "can be expressed in several human tissues, but mainly in the kidney" (*id.* at 16: 20-21).

7. The Specification provides no further details regarding the function of the protein of either SEQ ID NO: 2 or SEQ ID NO: 6.

8. The Specification discloses that the "identification and characterization of human genomic clones is helpful for identifying polymorphisms . . . , determining the genomic structure of a given locus/allele, and designing diagnostic tests" (*id.* at 10: 27 to 11: 1).

9. The Specification discloses:

> A G-or-C transversion polymorphism was identified at the sequence region corresponding to, for example, nucleotide position 212 of SEQ ID NO:1 which can result in the amino acid position corresponding to, for example, amino acid number 71 of SEQ ID NO:2 . . . being either a G or an A. An A-or-C transversion polymorphism was identified at the sequence region corresponding to, for example, nucleotide position 219 of SEQ ID NO:1 which can result in the amino acid position corresponding to, for example, amino acid number 73 of SEQ ID NO:2 . . . being either a K or a N.

(*Id.* at 16: 25 to 17: 2.)

*Principles of Law*

"Only after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal." *In re Brana*, 51 F.3d 1560, 1566 (Fed. Cir. 1995).

A utility must be both substantial and specific to satisfy 35 U.S.C. § 101. *In re Fisher*, 421 F.3d 1365, 1371 (Fed. Cir. 2005).

A substantial utility requires "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial'

utility requirement, an asserted use must show that that claimed invention has a significant and presently available benefit to the public." *Id.*

A specific utility is "a use which is not so vague as to be meaningless." *Id.* In other words, "in addition to providing a 'substantial' utility, an asserted use must show that that claimed invention can be used to provide a well-defined and particular benefit to the public." *Id.*

The *Fisher* court held that none of the uses asserted by the applicant in that case were either substantial or specific. The uses were not substantial because "all of Fisher's asserted uses represent merely hypothetical possibilities, objectives which the claimed ESTs, or any EST for that matter, *could* possibly achieve, but none for which they have been used in the real world." *Id.* at 1373. "Consequently, because Fisher failed to prove that its claimed ESTs can be successfully used in the seven ways disclosed in the '643 application, we have no choice but to conclude that the claimed ESTs do not have a 'substantial' utility under § 101." *Id.* at 1374.

> Furthermore, Fisher's seven asserted uses are plainly not 'specific.' Any EST transcribed from any gene in the maize genome has the potential to perform any one of the alleged uses. . . . Nothing about Fisher's seven alleged uses set the five claimed ESTs apart from the more than 32,000 ESTs disclosed in the '643 application or indeed from any EST derived from any organism. Accordingly, we conclude that Fisher has only disclosed general uses for its claimed ESTs, not specific ones that satisfy § 101.

*Id.*

"It is well established that the enablement requirement of § 112 incorporates the utility requirement of § 101." *Id.* at 1378.

*Analysis*

The Examiner bears the initial burden of showing that a claimed invention lacks patentable utility. We find that the reasoning set out in the Examiner's Answer meets that burden. The burden then "shift[s] to the applicant to provide rebuttal." *Brana*, 51 F.3d at 1566.

Appellants argue that "the present nucleotide sequences have utility in assessing gene expression patterns using high-throughput DNA chips" (Appeal Br. 9) and in mapping the human genome (*id.* at 11-13).

These uses do not meet the requirements of § 101. In this case, as in *Fisher*, the generic uses asserted by Appellants – assessing gene expression and mapping human chromosomes – are neither substantial nor specific. As in *Fisher*, these uses are "merely hypothetical possibilities, objectives which the claimed [human cDNAs], or any [human cDNA] for that matter, *could* possibly achieve, but none for which they have been used in the real world." *Fisher*, 421 F.3d at 1373 (emphasis in original). Therefore, they are not substantial utilities.

Nor are they specific utilities, because they could be asserted for any cDNA transcribed from any gene in the human genome. Because nothing about Appellants' asserted utilities sets the claimed nucleic acids apart from any other human cDNA, Appellants have "only disclosed general uses for [the] claimed [cDNAs], not specific ones that satisfy § 101." *Id.* at 1374.

Appellants also argue that, because the Specification discloses two polymorphic positions in SEQ ID NO: 1, "the present nucleic acid sequences have utility in diagnostic assays, such as forensic analysis, as described in

the specification as originally filed (see, for example, page 8, line 3, and page 10, line 27 through page 11, line 1)" (Appeal Br. 4).

This argument is not persuasive. The utility of a claimed invention is determined as of its filing date. *See In re Brana*, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995). The Specification does not disclose that the polymorphisms identified in SEQ ID NO: 1 make it useful for forensic analysis. The Specification's disclosure from page 10, line 27 to page 11, line 1 is quoted above (FF 8); it does not mention forensic analysis. The Specification's disclosure on page 8 is similar, in that it only mentions "diagnostic or prognostic assays" generically (see Spec. 8: 1-3). Appellants have not adequately shown that those skilled in the art would recognize the Specification's disclosure of "diagnostic" assays to be an assertion of utility based on forensic analysis.

In addition, the polymorphism-based utility is neither substantial nor specific. It is not substantial because it is merely a hypothetical possibility, an objective which the disclosed polymorphisms, or any polymorphism for that matter, *could* achieve, but not one for which the claimed nucleic acids have been used in the real world. *See Fisher*, 421 F.3d at 1373. It is not specific because nothing about the asserted utility sets apart the polymorphisms in the claimed nucleic acids from any other polymorphism found in the human genome. *See id.* at 1374.

*Conclusion of Law*

The Examiner did not err in concluding that none of the uses asserted for the claimed nucleic acids satisfy the requirements of 35 U.S.C. § 101.

## SUMMARY

We affirm the rejection of claims 1-4 and 6-13 under 35 U.S.C. §§ 101 and 112, first paragraph, because the Specification does not disclose a patentable utility for the claimed nucleic acids.

## TIME PERIOD FOR RESPONSE

No time period for taking any subsequent action in connection with this appeal may be extended under 37 C.F.R. § 1.136(a).

## AFFIRMED

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